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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,472

01/05/2006

Katia L Hvala

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01/12/2007

SMITHKLINE BEECHAM CORPORATION
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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/532,472

Applicant(s)

HVALA ET AL.

Examiner

Lisa V. Cook

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/22/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's preliminary amendment filed 4/22/05 is acknowledged. In the amendment filed therein the specification and claims 1-6 were modified. Claims 7 and 8 were cancelled. While new claim 9 was added. Currently claims 1-6 and 9 are pending and under consideration.

Priority

2. It is noted that this application appears to claim subject matter disclosed in prior *Application No. 0224688.2 filed in the United Kingdom on 10/23/02*. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii).

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This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

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3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Specifically the translated certified copy of Application No. 0224688.2 filed in the United Kingdom on 10/23/02 was received on 4/22/05.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered. See references cited in the specification.

5. The information disclosure statement filed 4/22/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

6. The disclosure is objected to because of the following informalities:

A. Page "1" is not numbered.

B. On page 4 line 1 the term "plastics" should be "plastic".

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7. The use of the trademarks has been noted in this application. (i.e. TWEEN on pages 4, 7, and 9). They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

8. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. A title more specific to the detection method involving a hepatitis B surface antigen comprising aluminium hydroxide would be more appropriate. (For example, Method and Kit for detecting hepatitis B surface antigen comprising aluminium hydroxide).

Abstract

9. The abstract of the disclosure is objected to because it includes legal phraseology "said" and unclear language (for example see "relates to" and "suitable"). Correction is required. See MPEP § 608.01(b).

10. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Objections

11. Claims 4 and 5 are objected to because of the following informalities: Claims 4 and 5 utilize acronyms (see BSA). Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim any prior art definition of the abbreviations. The terms should be defined in their first instance. The initial explanation will convey intended meaning of subsequent abbreviations in the claims. BSA is bovine serum albumin as defined in the specification on page 5. Please define.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "fragment thereof" in claim 1 is relative term, which renders the claim indefinite. The term "fragment" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to what if any fragments would maintain the activity of the antibody or sequence set forth in claims. Accordingly the claim is not clear.

B. In claim 1, in the *context* of a solid support is vague and indefinite. It is not clear how the solid support relates to the other reagents recited in the method. Will one of the reagents be bound to the solid support, will the reaction merely be conducted in a solid support (i.e. test tube), or will the assay be conducted independently of the solid support? It is suggested that the claim clearly indicated that the immunoglobulin is bound to a solid support in order to obviate this rejection. Please clarify the claim.

C. Claim 5 recites "*about* pH 9 and *about* 1% BSA". The term "about" in the claim is a relative term, which renders the claim vague and indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As recited the metes and bounds of the claim cannot be determined. It is not clear if the pH is 9 or some other number. It is not clear if the BSA is 1% or not. It is suggested that the actual number or range of number be included in the claim in order to obviate the rejection. Applicant is cautioned not to introduce new matter in to the claims. Appropriate correction is required.

D. Claims 6 and 9 are in improper Markush form and should include the "selection from the group consisting of" in the claim language. See MPEP 2173.05(h). Alternative Limitations I. MARKUSH GROUPS wherein Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 1925).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 1 and dependent claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an assay method for binding the hepatitis B surface antigen to anti-HBs rabbit polyclonal antiserum, it does not reasonably provide enablement for any and all immunoglobulins or fragments thereof binding any and all antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The disclosure does not set forth any fragments capable of meeting the claimed method and the only antigen exemplified is the hepatitis B surface antigen.

The skilled artisan cannot envision the detailed structure of the encompassed fragments and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

No disclosure, beyond the mere mention of hepatitis B surface antigen and the anti-HBs rabbit polyclonal antiserum is made in the specification. This is insufficient to support the claims drawn to the fragments thereof and the practice of the invention would cause undue experimentation.

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14. Claim 1 and dependent claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth a method of detecting a hepatitis B surface antigen in the presence of aluminium hydroxide with an anti-HBs rabbit polyclonal antiserum. See Examples 1 and 2 beginning at page 7 of the specification. Therefore the written description is not commensurate in scope with the claims drawn to the utility of any immunoglobulin or fragment thereof that binds any and all antigens.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117).

The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of anti-HBs rabbit polyclonal antiserum and the binding of hepatitis B surface antigens, the skilled artisan cannot envision the detailed structure of the encompassed all possible antigens and immunoglobulins or binding fragments thereof and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

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Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The monoclonal/polyclonal antibody itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of a compound/seq.id/etc. by only their functional activity does not provide an adequate written description of the genus.

The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by a sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description ...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

However, no disclosure, beyond the anti-HBs rabbit polyclonal antiserum and the binding of hepatitis B surface antigens is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only the method detecting the binding complex of anti-HBs rabbit polyclonal antiserum and hepatitis B surface antigens, but not any and all immunoglobulin or antigen binding fragment thereof would meet the full breadth of the claims as required by the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380).

Yamamoto et al. teach a method of detecting the hepatitis B surface antigen (HB surface antigen or HBsAg). This antigen was produced from aluminium hydroxide adjuvanted hepatitis B (HB) vaccines. See abstract and page 375. The HBsAg was desorbed from alum-gels and quantified. In the method a sandwich enzyme-linked immunosorbent assay (ELISA) is utilized. Specifically the adsorbed HBsAg is mixed with a solution of 0.4M sodium phosphate dibasic and 0.45M sodium citrate at pH 8.5. (Applicants basic buffer) The samples are then diluted with 0.5% casein-PBST (blocking agent). The specification teaches that PBS can be used as a blocking agent in the instant invention on page 5 – 3rd paragraph.

The mixtures were contacted with antibody plates (solid phase) coated with anti-HBs guinea pig polyclonal antibody (immobilized immunoglobulin) and incubated over night. An appropriate dilution of anti-HBs/a mAb was added and detected against controls and standards. See page 375 2nd column.

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Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) in view of Katz et al. (Journal of Virological Methods, Vol.25, 1989, pages 101-108).

Please see Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) as set forth above.

Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) differ from the instant invention in not specifically teaching assay procedures that are carried out with agitation.

However, Katz et al. teach a method of measuring viral antigens in aluminium hydroxide (AH) adjuvanted vaccines. See abstract. In the ELISA procedure the appropriate antiserum was diluted in 0.05M sodium carbonate buffer at pH 9.6 (basic buffer) and incubated overnight. The wells were then blocked with NFDM in PBS (blocking agent). The samples (commercial vaccines, unadjuvanted viral references, simulated vaccines, and controls) were added and agitated for 2 hours. After washing the plates were detected with a biotinylated anti-mouse IgG antibody, avidin-biotin-alkaline phosphatase conjugate, and *p*-nitrophenyl phosphate. See page 103- ELISA technique.

This procedure is taught to be an improvement over previous *in vitro* antigen quantitation methods because it may be used with intact vaccines but does not have the problems associated with the use of isotopes. It offers the convenience of ELISA without requiring antigen-AH dissociation and separation prior to measurement. See page 107 2nd paragraph. The method can be applied to AH adjuvanted vaccines as a class. Further, the method may minimize biological variability, time, expense, and humane difficulties associated with *in vivo* vaccine potency analysis. See page 107 last paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the agitation method of Katz et al. in the hepatitis B surface antigen detection of Yamamoto et al. because Katz et al. taught that his procedure was an improvement over previous *in vitro* antigen quantitation methods because it may be used with intact vaccines but does not have the problems associated with the use of isotopes. It offers the convenience of ELISA without requiring antigen-AH dissociation and separation prior to measurement. See page 107 2nd paragraph.

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One of ordinary skill in the art would have been motivated to employ the method of Katz et al. because it can be applied to AH adjuvanted vaccines as a class. Further, the method may minimize biological variability, time, expense, and humane difficulties associated with in vivo vaccine potency analysis. See page 107 last paragraph.

III. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) in view Foster et al. (U.S. Patent #4,444,879).

Please see Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) as set forth above.

Although Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) teach the reagents required by the claims; they do not specifically teach the reagents in kit configurations. In other words, the reference fails to teach the reagents as a kit. However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example.

In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit.

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Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

With respect to the kit containing written instructions, it is noted that although the reference does not specifically disclose that a kit would have instructions which teach how to use said kit, it would have been prima facie obvious to any one of ordinary skill in the art to include instructions which describe how to perform the assay. Applicants should note that the printed matter on the instructions in a kit cannot serve to define the kit over the prior art. See *In re Gulack* 217 USPQ (CAFC 1983).

IV. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) in view Kono et al. (JP 11201970 – Abstract Only).

Please see Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) as set forth above.

Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) differ from the instant invention in not teaching the use of BSA in their procedure.

However, Kono et al. teach a method for measuring hepatitis B surface antigens or antibodies with sensitized latex particles. In the procedure the immobilized reagents are treated with blocking agent and incubated with a non-immunoreactive protein and/or hydrolysis product to reduce background (non-specific binding) and largely increase specific signal for the immunoassay. The particles were treated with BSA, in the specific embodiment of the abstract.

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It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to employ BSA as exemplified by Kono et al. in the method of Yamamoto et al. (Biologicals, 1997, Vol.25, pages 373-380) because Kono et al. taught that in such procedures where the immobilized reagents are treated with [BSA] blocking agent and incubated with a non-immunoreactive protein and/or hydrolysis product it reduces background (non-specific binding) and largely increase specific signal for the immunoassay. See Kono et al. abstract.

Although Kono et al. disclose BSA the abstract is silent regarding the concentration. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine the optimal working concentration of BSA, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

17. For reasons aforementioned, no claims are allowed.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

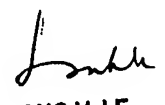
Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lisa V. Cook
Patent Examiner
Art Unit 1641
Remsen 3C-59
12/27/06



LONG V. LE 01/07/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600